K002598

NOV 2 2 2000

EMERSON

Medical Product Innovations Since 1928

J.H. EMERSON CO.
22 Cottage Park Avenue
Cambridge, MA 02140
Phone: 617-864-1414
Phone: 800-252-1414
Fax: 617-868-0841
Email:george@jhemerson.com
Internet: www.jhemerson.com

August 18, 2000

510(k) Summary of Safety and Effectiveness

Submitter: J. H. Emerson Co. Contact: George Emerson
22 Cottage Park Ave
Cambridge, MA 02140 Tel: 617-864-1414 Fax: 617-868-0841

Name of the Device: Emerson CoughAssist, Model CA-3000 with Automatic Timing, and Model CM-3000 with Manual Timing

Common / Usual Name: Secretion clearance device

Classification: Non-Continuous Ventilator (IPPB), Class II, per 21 CFR 868.5905

Predicate Device: Emerson In-Exsufflator, Model 2-CMH and Model 2-CA

Description of the Device:
The Emerson CoughAssist is a portable electric device which utilizes a blower and a valve to apply alternately a positive and then a negative pressure to a patient's airway in order to assist the patient in clearing retained bronchopulmonary secretions. It includes a means to adjust the pressure and suction levels applied, a pressure gauge to measure the pressures, and a means (optional) to reduce the positive pressure (inhale) flow. The air is delivered to and from the patient via a breathing circuit incorporating a flexible tube, a bacterial filter and either a facemask, a mouthpiece or an adapter to a tracheostomy or endotracheal tube.

Intended Use:
The Emerson CoughAssist assists patients in clearing retained bronchopulmonary secretions by gradually applying a positive pressure to the airway, then rapidly shifting to a negative pressure. This rapid shift in pressure, via a facemask, mouthpiece or an endotracheal or tracheostomy tube, produces a high expiratory flow rate from the lungs, simulating a cough.

Summary of Technological Characteristics:
The new CoughAssist was designed to achieve the same performance characteristics as the predicate device, but with improved appearance, quieter operation and simpler controls. It utilizes the same blower to generate the same pressures and flows, the same pressure gauge to measure the pressures applied, the same timing circuitry for cycling the valve in the automatic mode, the same patient breathing circuit, and has been tested for adequate electrical and mechanical safety and for electromagnetic compatibility. The main differences to the predicate device are a new plastic housing incorporating sound absorbing airflow chambers, a new valve design to enhance quieter air flow and simplify the controls, and the implementation of the inhale flow restrict feature as a built-in control, instead of as a separate assembly. None of these changes affects the safe and effective operation of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Mr. George P. Emerson
J.H. Emerson Company
22 Cottage Part Avenue
Cambridge, MA 02140

Re: K002598
Emerson CoughAssist
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II (two)
Product Code: 73 NHJ

Dear Mr. Emerson:

This letter corrects our substantially equivalent letter of November 22, 2000, regarding the Emerson CoughAssist. Our letter identified the product code as 73 BZD. This is in error; the correct product code is 73 NHJ as indicated above.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SPECIAL 510(K): DEVICE MODIFICATION

EMERSON COUGH-ASSIST

SECTION 3 - Indications for Use Statement

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: J. H. Emerson Co.

510(k) Number (if known): not known at this time

Device Name: Emerson CoughAssist, Models CA-3000 and CM-3000

Indications for Use:

For use on any patient unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease.

It may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube.

Clinical Settings: For use in a hospital / institutional environment, or in the home, given adequate training and a physician's prescription.

Patient Population: For use on adult or pediatric patients.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

K002598